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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/478,222	01/05/2000	DAVID S. GARVEY	102258.346	1404

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EXAMINER
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CELSA, BENNETT M

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/11/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

**Office Action Summary**

Application No.

09/478,222

Applicant(s)

Stamler et al.

Examiner

Bennett Celsa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 61-65 and 70-72 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61-65 and 70-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 22 6) ☐ Other:

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 1/10/03 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) (and Preliminary Amendment) based on parent Application No. 09/478,222 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Status of the Claims***

Claims 61-65 and 70-72 are currently pending and are under consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objection(s) and/or Rejection(s)***

In light of applicant's arguments and US Pat. No. 6,306,841 which is presumed valid, the rejections of:

a. claims 61-65 under 35 U.S.C. 103(a) as being unpatentable over Stamler et al. US Pat. No. 5,380,758 (1/10/95) and Gioco et al., U.S. Pat. No. 5,565,466 (10/96: filed 8/93) in the final office action (paper no. 16: dated 1/22/02); and

b. Claims 61-65 under the judicially created doctrine of provisional obviousness-type double patenting as being unpatentable over the pending claims (e.g claims 20-66, especially claims 20, 31-33) of copending Application No. 09/280,540 in view of Stamler et al. US Pat. No. 5,380,758 (1/10/95) and Gioco et al., U.S. Pat. No. 5,565,466

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C. Claims 61-65 under the judicially created doctrine of provisional obviousness-type double patenting as being unpatentable over the pending claims (e.g. claims 35-56, especially claims 41 and 44-46) of copending Application No. 09/306,809 in view of Stamler et al. US Pat. No. 5,380,758 (1/10/95) and Gioco et al., U.S. Pat. No. 5,565,466 are hereby withdrawn..

***Priority***

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

4. Applicant's claim for 35 U.S.C. 120 priority for  
*a. 09/145,143 (9/1/98) (US Pat. No. 6,294,517)* is granted.

However, Applicant's claim for 35 U.S.C. 120 priority for:

- I. PCT US 97/ 01294 (1/97) (Published as WO 97/27749);
- II. 08/714,313 (9/96) (US Pat. No. 5,994,294); and
- III. 08/595,732 (2/96) (US Pat. No. 5,932,538)

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is acknowledged BUT DENIED; since the above (I. II. And III) applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 61-65 and 70-72 of this application drawn to a method for treating **female impotence** with an S-nitrosothiol compound since the above applications demonstrate possession of using S-nitrosothiols to treat human male impotence but not human female impotence.

Accordingly, claim 61-65 and 70-72 are afforded the filing date of 9/1/98 for purposes of prior art.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 61-65 and 70-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Place et al. US Pat. No. 6,306,841 (10/01: *effective filing date Oct. 28, 1997*).

Place et al. describe and specifically claim the topical compositions (e.g. pharmaceutical) for use (e.g. see col. 2, especially lines 40-52; col. 4-6; examples/claims) of S-nitrosothiols (e.g. S-Nitroso-N-glutathione included in the present claims i.e. claim 65 item IV and claims 70 and 71) to treat female sexual dysfunction (e.g. impotence). E.g. See claims 1, 30 and 31.

8. Claims 61-65 and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Place et al. US Pat. No. 6,306,841 (10/01: *effective filing date Oct. 28, 1997*) and Stamler et al. WO 92/17445 US Pat. No. 5,380,758 (1/95).

Place et al. describe and specifically claim the topical compositions (e.g. pharmaceutical) for use (e.g. see col. 2, especially lines 40-52; col. 4-6; examples/claims) of S-nitrosothiols (e.g.

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S-Nitroso-N-glutathione included in the present claims i.e. claim 65 item IV and claims 70 and 71)) to treat female sexual dysfunction (e.g. impotence). E.g. See claims 1, 30 and 31.

The Place et al. reference teaching differs from the presently claimed invention by:

- A. failing to specifically recite specific S-nitrosothiol compounds which are presently claimed (e.g. see present claims 63 and 70) e.g. S-nitroso-N-acetylcysteine, S-nitroso-captopril, S-nitroso-homocysteine; and
- B. failing to teach S-nitrosothiol generics (I)-(iii) or compounds within these generics;

However, the Place et al. Reference does teach vasoactive agents NO releasing agents, such as the S-nitrosothiol compounds (e.g. see col. 9 and patent claims) can be employed interchangeably e.g. are functionally equivalent.

Stamler et al. teach that S-nitrosothiols such as S-nitroso-N-acetylcysteine, S-nitroso-captopril, S-nitroso-homocysteine and S-nitrosoglutathione; as well as S-nitrosothiol compounds within the presently claimed generics (I)-(iii) can be used interchangeably for the vasoactive effect (E.g. on smooth muscle). E.g. See Stamler at pages 1-6, examples and claims.

Accordingly, one of ordinary skill in the art would be motivated to utilize S-nitroso-N-acetylcysteine, S-nitroso-captopril, S-nitroso-homocysteine for the S-nitrosothiols (E.g. S-nitrosoglutathione) or a S-nitrosothiol compound within the presently claimed Generics I-III in the Place et al. method due to their functional equivalence as recognized by the Stamler and/or Place references.

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Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to utilize S-nitroso-N-acetylcysteine, S-nitroso-captopril, S-nitroso-homocysteine for the S-nitrosothiols (E.g. S-nitrosoglutathione) or an S-nitrosothiol compound within the Generics I-III in the the Place et al. method with a reasonable expectation of success.

***New Objection(s) and/or Rejection(s)***

***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).



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10. Claims 61-65 and 70-72 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 100-114 of copending Application No. 09/850,081. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '081 claims teach a method of treat female "sexual dysfunction" (e.g. female impotence as presently claimed) by the use of topical compositions comprising S-nitrosothiol compounds within the scope of the presently claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Relevant Prior Art (cumulative)***

1. Place et al. US Pat. No. 5,877,216 (3/99: filed Oct. 28, 1997). See entire document, especially col. 7 (lines 15-45).

**General information regarding further correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)  
September 9, 2003

BENNETT CELSA  
PRIMARY EXAMINER  
